5.26 CETUXIMAB, Solution for I.V. infusion 100 mg in 20 mL, Solution for I.V. infusion 500 mg in 100 mL Erbitux®, MERCK HEALTHCARE PTY LTD

1 Purpose of Submission

1.1 The Category 4 submission requested to increase the maximum amount for the existing listings of cetuximab (Erbitux®) to allow an alternative dosing regimen of 500 mg per m^2 body surface area (BSA) once every two weeks (herein referred to as 500 mg Q2W) in addition to the current dosing schedule of 400 mg per m^2 BSA on week 1 followed by 250 mg per m^2 BSA once every week (herein referred to as 250 mg Q1W) for the treatment of metastatic colorectal cancer (mCRC).

2 Background

2.1 Cetuximab is currently listed on the PBS as an Authority Required (STREAMLINED) listing for:

- First line treatment of RAS wild-type mCRC in combination with first line chemotherapy
- Second line treatment of RAS wild-type mCRC following first line chemotherapy or first line pembrolizumab for mismatch repair deficient (dMMR) mCRC
- *BRAF* V600E variant mCRC in combination with PBS-subsidised encorafenib
- Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx concomitant with radiotherapy

Registration status

2.2 Cetuximab was first registered in the Australian Register of Therapeutic Goods (ARTG) on 17 January 2005 for the treatment of patients with mCRC who express EGFR and whose disease has progressed or is refractory to irinotecan-based therapy. The Therapeutic Goods Administration (TGA) recommended doses for all indications required weekly intravenous infusion, with an initial dose of 400 mg per m^2 BSA followed by 250 mg per m^2 BSA Q1W.

2.3 The new dosing regimen of 500 mg Q2W for the treatment of mCRC was approved by the TGA for inclusion in the medicine's Product Information (PI) at the time of PBAC consideration.

Previous PBAC consideration

2.4 An increase in the maximum amount for the current cetuximab listings for mCRC and the addition of 500 mg Q2W have not been considered by the PBAC previously.

3 Requested listing

3.1 An abridged version of the requested listings is provided applicable to the relevant item codes/listings for mCRC. Secretariat suggested additions are in italics and deletions are in strikethrough.

Amend maximum amount for the mCRC listings:

MEDICINAL PRODUCT Form	**PBS item code**	**Max. Amount**	**№.of Rpts**
CETUXIMAB Injection	4436L(Public)} 7242E (Private)	~~880 mg~~ 1100 mg	0
Available brands			
Erbitux (cetuximab 100 mg/20 mL injection, 20 mL vial) (cetuximab 500 mg/100 mL injection, 100 mL vial)			

MEDICINAL PRODUCT Form	**PBS item code**	**Max. Amount**	**№.of Rpts**
CETUXIMAB Injection	10262D (Public) 10265G (Private)	~~550 mg~~ 1100 mg	18
Available brands			
Erbitux (cetuximab 100 mg/20 mL injection, 20 mL vial) (cetuximab 500 mg/100 mL injection, 100 mL vial)			

MEDICINAL PRODUCT Form	**PBS item code**	**Max. Amount**	**№.of Rpts**
CETUXIMAB Injection	4731B (Public)} 7273T (Private)	~~550 mg~~ 1100 mg	11
Available brands			
Erbitux (cetuximab 100 mg/20 mL injection, 20 mL vial) (cetuximab 500 mg/100 mL injection, 100 mL vial)			

MEDICINAL PRODUCT Form	**PBS item code**	**Max. Amount**	**№.of Rpts**
CETUXIMAB Injection	12820R (Public)} 12821T (Private)	~~880 mg~~ 1100 mg	0
Available brands			
Erbitux (cetuximab 100 mg/20 mL injection, 20 mL vial) (cetuximab 500 mg/100 mL injection, 100 mL vial)			

MEDICINAL PRODUCT Form	PBS item code	Max. Amount	№.of Rpts
CETUXIMAB Injection	12816M (Public) 12817N (Private)	~~550 mg~~ 1100 mg	11
Available brands			
Erbitux (cetuximab 100 mg/20 mL injection, 20 mL vial) (cetuximab 500 mg/100 mL injection, 100 mL vial)			

3.2 The submission requested amending all existing cetuximab listings for mCRC to increase the maximum amount from 880 mg to 1100 mg for initial treatment and from 550 mg to 1100 mg for continuing treatment to allow the 500 mg Q2W dosing regimen. No other changes to the current PBS restrictions were proposed.

3.3 The submission stated that the proposed maximum amount was derived from a BSA of 2.2 m^2, which is consistent with what was used for the Q1W regimen.

3.4 The PBAC noted it had previously considered that creating a separate listing with a different maximum amount and number of repeats to provide an alternative dosing regimen may lead to unnecessary complexity and potential ambiguity in the listings.

3.5 The PBAC noted that the requested maximum amount of 1100 mg with 18 repeats and 1100 mg with 11 repeats for the continuing treatment phases would provide sufficient amount for 38 weeks and 24 weeks of treatment, respectively, at the recommended dose of 500 mg per m^2 BSA Q2W. While the current number of repeat prescriptions would result in twice the duration of treatment for Q2W dosing compared to Q1W dosing, the PBAC noted that there is no criterion specifying the number of doses or length of treatment allowed.

3.6 The submission proposed the Special Pricing Arrangements for cetuximab remain unchanged.

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item.

Consumer comments

4.2 The PBAC noted and welcomed the input from the Medical Oncology Group of Australia (MOGA) via the Consumer Comments facility on the PBS website. The PBAC noted that no other consumer comments were received for this item.

4.3 The MOGA expressed support for the cetuximab submission seeking the addition of the fortnightly dosing regimen.

Clinical trials

4.4 The submission provided two meta-analyses comparing the Q1W and Q2W dosing regimens and supporting studies. These were presented to support the submission's claims that there were no significant differences between the two dosing regimens in primary outcomes such as overall survival (OS), progression free survival (PFS), objective response rate (ORR), disease-control rate (DCR), and adverse events.

Table 1: Studies presented in the submission

Publication title	Publication citation	Use in Clinical Evaluation
Matsuda A et al. Comparison between biweekly and weekly cetuximab in patients with metastatic colorectal cancer: a meta-analysis	Anticancer Research 2020; 40(6): 3469-3476	Efficacy and safety
Kasper S et al. Noninferiority of cetuximab every-2-weeks versus standard once-weekly administration schedule for the first-line treatment of RAS wild-type metastatic colorectal cancer	European Journal of Cancer 2021;144: 291-301	Efficacy and safety
Lamy FX et al. Comparative effectiveness of weekly versus every-2-weeks cetuximab in metastatic colorectal cancer in a US-insured population	Journal of Comparative Effectiveness Research 2020; 9(16): 1117-1129.	Efficacy and safety
Aggarwal H et al. Real-world comparison between weekly versus biweekly dosing of cetuximab for metastatic colorectal cancer	Journal of Comparative Effectiveness Research 2023; 12(2): e220143	Efficacy
Loft M et al. (2022) Compliance with Therapeutic Goods Association prescribing information: weekly or second weekly cetuximab for the treatment of metastatic colorectal cancer	Internal Medicine Journal.2023;, 53(9):1610-1617	Evidence for the use of Q2W dosing in Australian clinical practice

Source: Table 2-3, p19 of the submission

4.5 The TGA Delegate Overview (p21) highlighted key findings from the pharmacokinetic (PK)/pharmacodynamic (PD) modelling and comparative efficacy and safety data presented in the TGA submission. The following is drawn from the TGA Delegate Overview:

- At steady state, C_{min} was estimated to be 26% to 30% lower and C_{max} to be 26% higher with the 500 mg Q2W regimen compared with the 250 mg Q1W regimen. C_{avg} was estimated to be essentially the same for the two regimens. There's an overlap of the concentration profiles between the two dosing schedules, with cetuximab concentrations maintained throughout the 2-week dosing interval following 500 mg Q2W relative to 250 mg Q1W. Comparable exposure (AUC and C_{av}) to cetuximab was observed between the proposed Q2W regimen and the currently approved Q1W regimen.
- Evidence from available clinical studies supports that the Q2W regimen is not associated with a clinically significant loss of efficacy compared to the current Q1W regimen.
- No clear safety issues related to the frequency of dosing of cetuximab Q1W or Q2W were apparent in the literature supporting this submission. Overall safety of the cetuximab Q2W regimen appears to be comparable to that of the Q1W regimen.

4.6 As a Category 4 submission, no evaluation of the clinical evidence was undertaken.

Clinical claim

4.7 The submission claimed that, based on the clinical evidence presented, the Q2W dosing regimen of cetuximab for mCRC is non-inferior to the current Q1W dosing regimen in terms of comparative effectiveness and comparative safety.

4.8 The PBAC considered that the claim of non-inferior effectiveness was adequately supported by the clinical data.

4.9 The PBAC considered that the claim of non-inferior comparative safety was reasonable.

Economic analysis

4.10 The submission did not request changes to the current effective approved ex-manufacturer prices (AEMP) of cetuximab.

4.11 The proposed dispensed price for maximum amount (DPMA) for the requested maximum amount of 1100 mg was based on the current ex-manufacturer prices per 100 mg vial and 500 mg vial using the most efficient combination of cetuximab vials (1 x 100 mg vial and 2 x 500 mg vials).

4.12 The submission presented a comparison of the cost of cetuximab treatment between the Q1W and Q2W dosing regimens over 52 weeks (see Table 2), assuming the maximum amount dispensed. The cost of drug treatment with Q1W dosing comprises an initial treatment of 880 mg followed by weekly doses of 550 mg for continuing treatment, while under the Q2W dosing regimen, treatment costs include fortnightly doses of 1100 mg for both initial and continuing treatment.

Table 2: Cost comparison of cetuximab when administered weekly and fortnightly

Drug cost/patient/year*	250 mg/m² BSA Q1W	500 mg/m² BSA Q2W
First line treatment of mCRC		
Effective AEMP per 100 mg/20 mL injection vial	$	
Effective AEMP per 500 mg/100 mL injection via	$	
Treatment days per prescription	1 week	2 weeks
Cost of drug per 52 weeks (based on PBS maximum amount)	$	$
Difference in drug cost	-$	
Cost of treatment including parenteral administration scheduled fee (MBS item code 13950)	$118.3 x 52 = $	$118.3 x 26 = $
Difference in treatment cost per year	-$	
Second line treatment of mCRC		
Effective AEMP per 100 mg/20 mL injection vial	$	
Effective AEMP per 500 mg/100 mL injection via	$	
Treatment days per prescription	1 week	2 weeks
Cost of drug per 52 weeks (based on PBS maximum amount)	$	$
Difference in drug cost	- $	
Cost of treatment including parenteral administration scheduled fee (MBS item code 13950)	$118.3 x 52 = $	$118.3 x 26 = $
Difference in treatment cost per year	-$	

Source: Tables 3-1 and 3-2 of the submission and UCM-Release-3-Workbook-v1081
AEMP = approved ex-manufacturer price, mCRC = metastatic colorectal cancer.
*The drug cost per patient over 52 weeks includes both initial and continuing treatment, accounting for the maximum amount dispensed.

Estimated PBS usage and financial implications

4.13 A market share approach was used to estimate the utilisation and financial impact of adding the 500 mg Q2W dosing regimen to the PBS for mCRC.

4.14 The submission cited an analysis from seven Melbourne hospitals to evaluate the real-world utilisation of the Q1W and Q2W dosing regimens for mCRC from January 2010 to August 2019 (Loft et al., 2022). It was reported that over 70% of patients with mCRC commenced treatment with cetuximab using Q2W dosing. The submission assumed that the finding of this study would align with the current prescription trends of cetuximab in Australia more broadly. Based on 30% and 70% of patients receiving Q1W dosing and Q2W dosing, respectively, the submission estimated that 46.2% of the current cetuximab prescriptions for mCRC are dispensed for Q1W dosing and 53.8% for Q2W dosing.

4.15 The submission assumed that 75% of current prescriptions for Q1W dosing would be replaced by prescriptions for Q2W dosing over the six years following the addition of Q2W dosing on the PBS. The sponsor noted that the uptake rate of 75% was based on clinician advice. No further information was provided in the submission to validate this claim.

4.16 The submission estimated a saving to the PBS/RPBS of $0 to < $10 million in Year 6 from the addition of Q2W dosing, with a total net saving to the PBS/RPBS of $0 to < $10 million over the first 6 years of listing. This is summarised in Table 2 below.

Table 3: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated total number of cetuximab scripts dispensed						
before adding 500 mg/m^2 BSA Q2W*	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
reduced number of scripts due to 500 mg/m^2 BSA Q2W	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]
after adding 500 mg/m^2 BSA Q2W	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Estimated financial implications of adding 500 mg/m^2 BSA Q2W						
Cost to PBS/RPBS less copayments	[redacted][3]	[redacted][3]	[redacted][3]	[redacted][3]	[redacted][3]	[redacted][3]
Estimated financial implications without the inclusion of 500 mg/m2 BSA Q2W						
Cost to PBS/RPBS less copayments	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][4]
Net financial implications						
Net impact to PBS/RPBS	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][4]
Net impact to MBS	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][4]
Net impact to Government	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][4]

Source: Financial table workbook (cetuximab_UCM) supplied with the submission
Abbreviations: MBS = Medical Benefits Scheme; PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme; BSA = body surface area.
*An annual growth rate of 2%, derived from the number of PBS and RPBS services dispended from 2018 to 2022 for mCRC, was applied to estimate the prescription volumes for the next six years.
The redacted values correspond to the following ranges:
[1] 10,000 to < 20,000
[2] 500 to < 5,000
[3] $0 to < $10 million
[4] net cost saving

4.17 The submission considered that the addition of the 500 mg Q2W dosing regimen is not expected to increase the treatment uptake rate of patients treated with cetuximab or alter the usage patterns of other PBS-listed medicines.

4.18 The submission claimed the 500 mg Q2W regimen would offer treatment flexibility and convenience, reducing patient burden through less frequent dosing and hospital visits. This is expected to lead to a decrease in resource utilisation in infusion centres, contributing to a reduction in administrative burden.

5 PBAC Outcome

5.1 The PBAC recommended increasing the maximum amount for the current listings of cetuximab to allow an alternative dosing regimen of 500 mg per m^2 body surface area (BSA) once every two weeks in addition to the current dosing schedule of 400 mg per m^2 BSA on week 1 followed by 250 mg per m^2 BSA once every week for the treatment of metastatic colorectal cancer (mCRC).

5.2 The PBAC considered that it is reasonable to amend all current cetuximab listings for mCRC to increase the maximum amount for initial treatment from 880 mg to 1100 mg and for continuing treatment from 550 mg to 1100 mg to allow the 500 mg Q2W dosing regimen. This decision aligns with its previous approach to minimise additional item code creation when providing a new dosing regimen.

5.3 The PBAC noted that retaining the current number of repeats would result in prescriptions providing an increased duration of treatment with Q2W dosing. However, the PBAC also noted that there are no specific criteria limiting the number of doses or duration of treatment with cetuximab in the current restrictions. The PBAC expected that prescribers would closely monitor patients during treatment and discontinue cetuximab upon the occurrence of disease progression under the treatment criterion; "Patient must not have progressive disease". As such, the PBAC considered that it was appropriate to maintain the current number of repeats.

5.4 The PBAC noted that the clinical data indicated no significant differences in efficacy and safety between the Q1W and Q2W regiments. The PBAC considered that the effectiveness and safety of the two dosing regimens would likely be comparable.

5.5 The PBAC noted that the submission estimated a total net saving to the PBS/RPBS of $3.9 million over the first 6 years of listing, based on no changes to the current AEMP of cetuximab vials. The PBAC acknowledged that there may be savings to the Government associated with the addition of Q2W dosing, noting fewer prescriptions dispensed for Q2W dosing compared to Q1W dosing for the same duration of treatment that would result in a decrease in administrative costs. However, the PBAC considered that the extent of these savings was uncertain due to the unknown uptake rate of the new Q2W dosing and the claimed extensive use of this dosing regimen in current clinical practice.

5.6 The PBAC considered that increasing the maximum amount to allow Q2W dosing of cetuximab would provide patients with greater flexibility and convenience, given the new dosing requires less frequent infusion sessions and hospital visits. Furthermore, it would result in more efficient resource allocation for infusion centres and ease the administrative burden for clinicians.

5.7 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

6 Recommended listing

6.1 Amend existing listed amount to appear as follows:

MEDICINAL PRODUCT **Form**	**PBS item code**	**Max. Amount**	**№.of Rpts**
CETUXIMAB Injection	4436L(Public)} 7242E (Private)	~~880 mg~~ *1100 mg*	0

Available brands
Erbitux (cetuximab 100 mg/20 mL injection, 20 mL vial) (cetuximab 500 mg/100 mL injection, 100 mL vial)

Restriction Summary: 11994 / Treatment of Concept: 12045	
Concept ID	**Category / Program:** Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals
	Prescriber type: ☒ Medical Practitioners
	Restriction type: ☒ Authority Required (STREAMLINED)
	Administrative Advice: Special Pricing Arrangements apply.
	Administrative Advice: This drug is not PBS-subsidised for use in combination with another anti-EGFR antibody or in combination with an anti-VEGF antibody.
	Indication: Metastatic colorectal cancer
	Treatment Phase: Initial treatment
	Clinical criteria:
	Patient must have RAS wild-type metastatic colorectal cancer
	AND
	Clinical criteria:
	Patient must have a WHO performance status of 2 or less
	AND
	Clinical criteria:
	The condition must have failed to respond to first-line chemotherapy; or
	The condition must have progressed following first-line treatment with pembrolizumab for dMMR mCRC
	AND
	Clinical criteria:
	The treatment must be as monotherapy; or
	The treatment must be in combination with chemotherapy
	AND
	Clinical criteria:
	The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition
	Prescribing Instructions: Patients who have progressive disease on panitumumab are not eligible to receive PBS-subsidised cetuximab.
	Prescribing Instructions: Patients who have developed intolerance to panitumumab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised cetuximab.

Restriction Summary: 4908 / Treatment of Concept: 4908	
	Indication: Metastatic colorectal cancer
	Treatment Phase: Initial treatment
	Clinical criteria:
	Patient must have RAS wild-type metastatic colorectal cancer
	AND
	Clinical criteria:
	Patient must have a WHO performance status of 0 or 1
	AND
	Clinical criteria:
	The condition must be previously untreated

	AND
	Clinical criteria:
	The treatment must be in combination with first-line chemotherapy
	AND
	Clinical criteria:
	The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition

MEDICINAL PRODUCT **Form**	**PBS item code**	**Max. Amount**	**№.of Rpts**
CETUXIMAB Injection	10262D (Public) 10265G (Private)	~~550 mg~~ *1100 mg*	18
Available brands			
Erbitux (cetuximab 100 mg/20 mL injection, 20 mL vial) (cetuximab 500 mg/100 mL injection, 100 mL vial)			
Restriction Summary: 4912 / Treatment of Concept: 4912			

Concept ID		**Category / Program:** Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals
		Prescriber type: ☒ Medical Practitioners
		Restriction type: ☒ Authority Required (STREAMLINED)
		Administrative Advice: Special Pricing Arrangements apply.
		Administrative Advice: This drug is not PBS-subsidised for use in combination with another anti-EGFR antibody or in combination with an anti-VEGF antibody.
		Administrative Advice: This drug is not PBS-subsidised when chemotherapy partners are switched whilst maintaining an anti-EGFR antibody backbone in the face of progressive disease.
		Administrative Advice: The treatment must not exceed a single course of therapy with this drug for metastatic colorectal cancer in a patient's lifetime.
		Indication: Metastatic colorectal cancer
		Treatment Phase: Continuing treatment
		Clinical criteria:
		Patient must have received an initial authority prescription for this drug for first-line treatment of RAS wild-type metastatic colorectal cancer
		AND
		Clinical criteria:
		Patient must not have progressive disease
		AND
		Clinical criteria:
		The treatment must be in combination with first-line chemotherapy
		AND
		Clinical criteria:
		The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition

MEDICINAL PRODUCT **Form**	**PBS item code**	**Max. Amount**	**№.of Rpts**
CETUXIMAB Injection	4731B (Public)} 7273T (Private)	~~550 mg~~ *1100 mg*	11

Available brands
Erbitux (cetuximab 100 mg/20 mL injection, 20 mL vial) (cetuximab 500 mg/100 mL injection, 100 mL vial)

Restriction Summary: 12015 / Treatment of Concept: 12016	
Concept ID	**Category / Program:** Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals
	Prescriber type: ☒ Medical Practitioners
	Restriction type: ☒ Authority Required (STREAMLINED)
	Administrative Advice: Special Pricing Arrangements apply.
	Administrative Advice: This drug is not PBS-subsidised for use in combination with another anti-EGFR antibody or in combination with an anti-VEGF antibody.
	Administrative Advice: This drug is not PBS-subsidised when chemotherapy partners are switched whilst maintaining an anti-EGFR antibody backbone in the face of progressive disease.
	Administrative Advice: The treatment must not exceed a single course of therapy with this drug for metastatic colorectal cancer in a patient's lifetime.
	Indication: Metastatic colorectal cancer
	Treatment Phase: Continuing treatment
	Clinical criteria:
	Patient must have received an initial authority prescription for this drug for treatment of RAS wild-type metastatic colorectal cancer after failure of first-line chemotherapy; or
	Patient must have received an initial authority prescription for this drug for treatment of RAS wild-type metastatic colorectal cancer after failure of treatment with first-line pembrolizumab for dMMR mCRC
	AND
	Clinical criteria:
	Patient must not have progressive disease
	AND
	Clinical criteria:
	The treatment must be as monotherapy; or
	The treatment must be in combination with chemotherapy
	AND
	Clinical criteria:
	The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition
	Prescribing Instructions: Patients who have progressive disease on panitumumab are not eligible to receive PBS-subsidised cetuximab.
	Prescribing Instructions: Patients who have developed intolerance to panitumumab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised cetuximab.

MEDICINAL PRODUCT Form	PBS item code	Max. Amount	№.of Rpts
CETUXIMAB Injection	12820R (Public)} 12821T (Private)	~~880 mg~~ *1100 mg*	0
Available brands			
Erbitux (cetuximab 100 mg/20 mL injection, 20 mL vial) (cetuximab 500 mg/100 mL injection, 100 mL vial)			
Restriction Summary: 12483 / Treatment of Concept: 12483			
Concept ID	**Category / Program:** Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals		
	Prescriber type: ☒ Medical Practitioners		
	Restriction type: ☒ Authority Required (STREAMLINED)		
	Administrative Advice: Special Pricing Arrangements apply.		
	Indication: Metastatic colorectal cancer		
	Treatment Phase: Initial treatment		
	Clinical criteria:		
	The treatment must be in combination with PBS-subsidised encorafenib for this condition		

MEDICINAL PRODUCT Form	PBS item code	Max. Amount	№.of Rpts
CETUXIMAB Injection	12816M (Public) 12817N (Private)	~~550 mg~~ *1100 mg*	11
Available brands			
Erbitux (cetuximab 100 mg/20 mL injection, 20 mL vial) (cetuximab 500 mg/100 mL injection, 100 mL vial)			
Restriction Summary: 12470 / Treatment of Concept: 12470			
Concept ID	**Category / Program:** Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals		
	Prescriber type: ☒ Medical Practitioners		
	Restriction type: ☒ Authority Required (STREAMLINED)		
	Administrative Advice: Special Pricing Arrangements apply.		
	Indication: Metastatic colorectal cancer		
	Treatment Phase: Continuing treatment		
	Clinical criteria:		
	The treatment must be in combination with PBS-subsidised encorafenib for this condition		

This restriction may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.

7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available

through the PBS. The PBAC welcomes applications containing new information at any time.

8 Sponsor's Comment

Merck welcomes PBAC's recommendation to increase the maximum amount of current cetuximab listings for the treatment of metastatic colorectal cancer without creating additional PBS item codes to allow addition of the two-weekly dosing regimen on the PBS. Merck welcomes PBAC's acknowledgement that increasing the maximum amount to allow two-weekly dosing of cetuximab would provide patients with greater flexibility and convenience, given the new dosing requires less frequent infusion sessions and hospital visits. Furthermore, it would result in more efficient resource allocation for infusion centres and ease the administrative burden for clinicians.